General

Guideline Title

Clinical practice guideline for diabetes mellitus type 1.

Bibliographic Source(s)

Working Group of the Clinical Practice Guideline on Diabetes Mellitus Type 1. Clinical practice guideline for diabetes mellitus type 1. Madrid (Spain): Basque Office for Health Technology Assessment, Osteba; 2012 May 1. 345 p. [644 references]

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

Definitions of the quality of evidence (1-4, I-IV) and the strength of recommendations (A-D, and GCP) are presented at the end of the "Major Recommendations" field.

Definition and Diagnostic Criteria of Diabetes Mellitus Type 1

Autoantibodies in the Diagnosis of Diabetes Mellitus Type 1

B: Regular measurement of the C-peptide or specific antibodies to confirm the diagnosis of diabetes mellitus type 1 is not advisable, but its use

should be considered to determine the etiology of autoimmune diabetes in doubtful cases.

Predictors of 'Spontaneous Remission'

GCP: The patient and their caregivers (in case they are children) should be informed about the possibility of entering into a spontaneous remission or "honeymoon" stage within months of the diagnosis of diabetes mellitus type 1 that would imply a reduction of insulin doses. Likewise, it is necessary to point out that this entails no cure for the disease and that after this period insulin doses will have to be increased again.

Genetic Study to Rule Out Maturity Onset Diabetes of the Young (MODY) Diabetes

D: In cases in which mild continuous hyperglycaemia is identified in a young person, without obesity and/or diabetes history of mild to two generations, in the absence of antipancreatic autoimmunity and with human leukocyte antigen (HLA) not compatible to diabetes mellitus type 1, MODY 2 (mutations in the glucokinase gene) diabetes should be ruled out.

D: If hyperglycaemia is more severe and progressive, it is recommended to rule out MODY 3 (mutations in the *HFN1A* gene) diabetes.

D: If genetic testing were negative for MODY 2 and MODY 3, the rest of MODY varieties would have to be ruled out.

Study of Antibodies to Rule Out Other Autoimmune Multiglandular Diseases

B: Autoimmune thyroid disease and celiac disease at the onset of diabetes mellitus type 1 in children and adolescents should be ruled out.

GCP: This study should be done every two years for the first 10 years of disease progression and then every five years.

Diabetes Education

Structured Education Aimed at Families and/or Patients with Diabetes Mellitus

A: All patients with diabetes mellitus type 1 should have access to a diabetes education program delivered by a multidisciplinary team (doctors, nurse educators, psychologists, dieticians, etc.) with specific skills in diabetes, both in the diagnosis stage and subsequently, based on the patient's needs.

A: In cases of repeated hypoglycaemia, the patient with diabetes and their families should be offered a specific educational program.

Education Aimed at Patients and Family

D: Structured diabetes education should be provided in the following circumstances:

- At the time of diagnosis (survival education)
- In the period following diagnosis (deepening and reinforcement education)
- In the long term: on periodic reviews on self-care and educational needs, depending on the achievement or not of the objectives agreed between the patient and the practitioner

D: Structured diabetes education should be provided to the following people:

- All patients diagnosed with diabetes mellitus type 1
- Parents and carers in cases where there is dependency because of age or disability
- The people who make up the school environment of children or adolescents: teachers, caregivers, etc.

D: Professionals who must provide structured diabetes education:

- Multidisciplinary teams: the members of these teams should have competencies and skills to convey information effectively. There must be enough professionals available to organize regulated educational programs for groups. The team should include, at least, specialists in endocrinology, pediatric endocrinology and diabetes nurse educators. It is also desirable that psychologists were included in these teams for people who may need them.
- At extra sanitary level the associations of people with diabetes, who provide educational programs for specific groups, play a key role (camps for children, elderly patients, informative talks, gatherings, etc.)

The members of the educational team should be characterized not only by their capacity for empathy, but also for their flexibility and ability to communicate.

D: Methods and materials used to provide structured education on diabetes:

- Attendance-based training sessions using audiovisual media, food, and objects related to learning about food: games, plastic food, and descriptive flashcards to facilitate understanding.
- Complementary methods:
    - Books and leaflets: a great effort should be made for the guidelines contained in these materials to be useful in the daily management of the disease.
    - Internet: due to the lack of standardized certifications about the origin, source and credibility of the online content, it is important to facilitate reliable reference website addresses and that the learner has a basic knowledge of the disease and its clinical management for proper interpretation of the information available.
    - Media: Newspapers, magazines, television and radio.
    - Cards, identification bracelets or necklaces and transport equipment for carrying and storing of insulin devices.
    - Data on associations of people with diabetes and other support groups.
    - Psychological counseling at the time of diagnosis of diabetes mellitus type 1.
    - Provide contact phone numbers in case of emergency.
    - Other information and communication technologies (telemedicine, blogs, etc.)

D: Aspects that structured diabetes education should include:

Level 1: Survival education

- What is diabetes mellitus. Types of diabetes.
- Symptoms of diabetes mellitus type 1
- What is insulin. Treatment with insulin.
- What is glucose and blood glucose goals
- Basic dietary advice
- Acute complications (hypoglycaemia, hyperglycaemia and ketosis)
- Special situations (diabetes mellitus type 1 in school, intercurrent diseases, gastronomic celebrations, vents, travels, etc.)
- Psychological impact of the disease, identification of prior beliefs, fears and expectations
- Techniques for the injection of insulin and glucagon
- Self-analysis of capillary blood glucose meter techniques
- Urine self-analysis technique, measurement of ketonuria, ketonemia and interpretation of results

Level 2: Advanced education

- Physiopathology, epidemiology and classification of diabetes
- Types of insulin: absorption, action profiles, variability and adjustments
- Food planning: qualitative and quantitative advice on immediate and fibre intakes, with special attention to carbohydrate intake
- Control objectives, including the concept of glycosylated haemoglobin
- Reinforcement of knowledge of acute complications
- Problem solving and adjustment of treatment
- Micro- and macrovascular complications: prevention and monitoring
- Adjustment of insulin patterns and feeding on special situations, such as exercising, holidays and traveling
- Tobacco, alcohol and other drugs
- Adjustment to work and driving
- Sexuality, contraception, teratogenic drugs, pregnancy and breast-feeding
- Updated research on diabetes mellitus type 1
- Continuous infusion pumps
- Foot care

D: Methods for teaching structured education about diabetes:

Several methods have been used successfully in diabetes education. The choice of one or the other depends on the characteristics of the patient, the disease stage and the capacity of each team or health care center.

Individualized education

- An intensive individualized program should be provided to newly diagnosed diabetes mellitus type 1 patients and in the case of pregnancy.

Education groups

- The groups should be organized according to age, socio-cultural background, etc. It is desirable that family members and friends of patients also participate in the groups. Group education should include the following aspects:
    - Structured training by explicative lectures
    - Discussion groups, with analysis of the perceptions and experiences of all group members
    - Identification of fears and anxieties
    - Assessment of needs and expectations
    - Manifestation of personal experiences regarding hypoglycaemia, physical activity, stress response, etc.
    - Audiovisual methods
    - Support educational material, which the patient can read at home

D: Characteristics which structured education programs on diabetes must contain:

- Actively involve patients in all the stages of the educational program (design, implementation, evaluation), providing them with the tools to make the best decisions about their own health.
- Set the benefits of learning new skills, including the daily monitoring of the treatment.
- Assess the educational needs of each patient.
- Assess patients' personal perceptions.
- Be flexible so that the programs are adapted to the specific educational, social and cultural needs.
- Have educational goals agreed with patients. The expectations of professionals and patients may differ, so it is important to agree on common objectives, which may vary over time and require continuous review. Any proposed therapeutic target should be achievable.
- Have a syllabus and a fixed schedule.
- Do not create a very concentrated program and schedule frequent breaks.
- Schedule lectures that do not exceed 25% of the total time, and include a time for asking and answering questions.
- Pay attention to the choice of words and expressions, avoiding an overly technical language.
- Provide standardized and consistent information between different team members.
- Plan meetings between the professionals involved, to exchange ideas, discuss cases and review the program and methods.
- Facilitate that adults participate in their own health care by giving them the possibility to make judgments and choices about their own care.
- It is advisable to establish a dynamic contact process with the patient, either through visits, group discussions between patients, telephone contact or computer systems.

D: Other considerations:

- Discuss any changes that have taken place at biomedical level (new insulin requirements, glycaemia monitoring strategies, onset of ocular complications, etc.).
- Evaluation: the educational program and the goals should be assessed by process and results indicators.
- Provision should be done of all the information needed to enable the development of the therapeutic education program: space required, enough qualified personnel, necessary educational materials and work agendas and schedules.

Community Support Arrangements

B (Adults)/A (children): Updated information should be provided to adults, children and adolescents with diabetes mellitus type 1 as well as to their families at the time of diagnosis, and periodically thereafter, on the existence of diabetes support groups, both locally and nationally and how to contact them (see Appendix 11.2 in the original guideline document).

B: The diabetes care teams should be aware that a poor psychosocial support has a negative impact on various outcomes of diabetes mellitus type 1 in children and young patients, including glycaemic control and self-esteem.

A: Young patients with diabetes mellitus type 1 should be offered specific support strategies, such as tutoring on self-analysis supported by solution to problems, how to improve their self-esteem and glycaemic control, and retreats to exchange experiences, to reduce conflict related to diabetes among family members.

GCP: There is no formal relationship between the health care services and diabetes associations. This relationship can be beneficial as long as the performances are confluent. It would be advisable for a physician and/or diabetes nurse educator to participate in the diabetic associations in order to provide technical support for the activities to be developed.

Feeding

Feeding Specifications for People with Diabetes Mellitus Type 1

General Recommendations

GCP: Nutrition recommendations for a healthy lifestyle valid among the general population are also appropriate for people with diabetes mellitus type 1. Currently, there are several insulin options available, allowing to adapt the best suited insulin regimen to the taste preferences and food choices of people with diabetes mellitus type 1 in the context of a healthy diet.

GCP: The improvement in glycaemic control with insulin therapy is usually associated with increased body weight. As potential weight gain may adversely affect blood glucose, lipids, blood pressure and health in general, it is desirable to prevent it.

GCP: Although the carbohydrate content of food determines the insulin dose, special attention should also be given to the total intake of proteins and fats.

Carbohydrates

A: The insulin dose should be adjusted to the carbohydrate intake in people with diabetes mellitus type 1. This recommendation should be accompanied by the support of health professionals through a comprehensive nutrition education.

A: In patients with diabetes mellitus type 1, foods with table sugar can be replaced with foods containing other sources of carbohydrates.

GCP: If the patient eats food with high sugar content, its absorption should be slowed down by associating their food intake with fat or fibre.

Artificial Sweeteners

B: In patients with diabetes mellitus type 1 it is preferable to use artificial sweeteners which do not interfere with glycaemic increase (see Appendix 2 in the original guideline document).

B: It is recommended to prevent the abuse of drinks and foods sweetened with fructose. This recommendation should not be extended to the fructose contained in fruits and vegetables, as these are healthy foods that provide small amounts of fructose in a normal diet.

Glycaemic Index

GPC: For patients with diabetes mellitus type 1 who are assessing dietary planning based solely on the glycaemic index of foods, health professionals should inform them about the lack of conclusive evidence regarding its benefits.

Fibre

A: Recommendations for fibre intake in patients with diabetes mellitus type 1 are similar to those of the general population: therefore, a diet containing 25 to 30 g fibre/day, with special emphasis on the consumption of soluble fibre (7 to 13 g) is advisable.

Proteins in Patients with Nephropathy

A: In people with diabetic nephropathy, a protein intake of less than 0.8 g/kg/day is recommended.

A: In people with advanced diabetic nephropathy (chronic renal failure in phases 3-5), a possible hypoalbuminemia should be monitored by modifying the protein and caloric intake to prevent malnutrition.

Diet for the Prevention and Treatment of Cardiovascular Disease

B: Nutritional interventions should be implemented to improve metabolic control and lipid profile in the prevention and treatment of cardiovascular disease in patients with diabetes mellitus type 1.

Eating Plan Recommended for Patients with Diabetes Mellitus Type 1

GCP: A meal plan must be set adjusted to age, insulin dosage, physical activity, weight and personal situation (pregnancy, hypercholesterolemia, etc.) of the patient and his/her ability to understand.

Exercising

Benefits of Exercise in Patients with Diabetes Mellitus Type 1

A: Patients with diabetes mellitus type 1 are recommended to practice physical exercise, especially for its positive effect on the lipid profile and on blood pressure.

A: Children and adolescents with diabetes mellitus type 1 should be highly recommended to do physical exercise as there is some evidence showing its benefits on metabolic control.

Type, Intensity and Duration of Physical Exercise in People with Diabetes Mellitus Type 1

A: People with diabetes mellitus type 1 should be encouraged to perform regular physical exercise.

A: People with diabetes mellitus type 1 should be recommended moderate physical exercise for at least 135 minutes a week, without being more than two consecutive days without doing physical exercise.

GCP: People with diabetes mellitus type 1 and their families should be informed that they can participate in all forms of exercise, providing they know how to perform the appropriate adjustments to the intake and insulin.

GCP: The people with diabetes mellitus type 1 who wish to participate in less common/or specific risk sports should be educated on this matter; however, it is not advisable to perform these alone.

GCP: People with diabetes mellitus type 1 and their families should be encouraged to monitor blood glucose levels before and after exercise to learn about the glycaemic response in different conditions of exercise, and make the necessary adjustments before, during or after it.

GCP: People with diabetes mellitus type 1 and their families should be informed about late hypoglycaemia risk in situations of intense and/or prolonged exercise, to take the necessary precautions.

GCP: People with diabetes mellitus type 1 and their families should be informed that exercise is contraindicated if there are high levels of blood glucose and/or ketones in the blood or urine.

GCP: Young people and adults with diabetes mellitus type 1 who want to do intense physical exercise should consult a doctor to rule out microvascular complications that contraindicate it.

Glycaemic Control

Glycosylated Haemoglobin (HbA_{1c})

A: It is recommended to inform people with diabetes mellitus type 1 and their families of the benefits of a long-term metabolic control with HbA_{1c} levels below 7% (46 mmol/mol) without disabling hypoglycaemia, therefore the care measures must be designed to achieve these aims.

GCP: The aims of the treatment should be individualized and agreed with the patient, assessing the risks and benefits.

GCP: The goals should be less demanding in people with a history of severe hypoglycaemia, no recognition of hypoglycaemia, patients with limited life expectancies, young children and patients with chronic concomitant diseases.

D: The HbA_{1c} results should be issued in two types of units simultaneously on all laboratory reports: National Glycohemoglobin Standardization Program/Diabetes Control and Complication Trial (NGSP/DCCT) % units (with a decimal) and International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) (mmol/mol) (no decimals) units.

Systems of Continuous Glucose Monitoring

A: Although continuous glucose monitoring can be an instrument to improve or maintain metabolic control in patients motivated and trained in intensive care, if it is used continuously, its universal use is not recommended for people with diabetes mellitus type 1.

Inpatient or Outpatient Clinical Management of Patients with Diabetes Mellitus Type 1 at the Time of Diagnosis

A: At the time of diagnosis of diabetes mellitus type 1 outpatient care and education can be offered versus hospital management, according to the clinical needs, circumstances and wishes of the patient and the patient's home proximity to the health services, provided that there are no acute complications and that enough health infrastructure can be guaranteed to ensure adequate health care quality.

Preparations of Insulin in the Treatment of Patients with Diabetes Mellitus Type 1

Fast-Acting Analogues vs. Human Insulin

Adults

A: In adults with diabetes type 1 fast-acting insulin analogues cannot be recommended in a generalized way, as they have similar effectiveness to human insulin and there is no evidence to ensure its long-term safety. However, as these provide greater flexibility in their administration, patients are more satisfied, which may improve adherence to the treatment. It is therefore advisable to make an individualized assessment of the treatment.

Children and Adolescents

A: In children and adolescents with type 1 diabetes, the widespread use of fast-acting insulin analogues cannot be recommended, since they have similar effectiveness to human insulin and there is no evidence to ensure their long-term safety. However, as they do provide greater flexibility in their administration, patient's satisfaction increases, thus it may improve adherence to the treatment. It is therefore advisable to make an individualized assessment of the treatment.

Pregnant Women

A: In pregnant women with diabetes type 1, the use of human insulin is recommended by its demonstrated efficacy and its greater safety against the use of analogues.

Slow-Acting Analogues vs. Human Insulin

Glargine vs. Intermediate-acting Human Insulin (Neutral Protamine Hagedorn [NPH])

Adults

B: The use of glargine versus intermediate-acting human insulin (NPH) can be recommended in adults, although the lack of data on long-term safety should be noted.

GCP: Regarding the current safety of glargine, it is recommended not to take any regulatory action or instruct a change of treatment to the patients using insulin glargine until the results of the evaluation of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) are published.

Children and Adolescents

B: The widespread use of glargine is not recommended in children with diabetes mellitus type 1 over 6 years, since no benefit has been demonstrated for the use of NPH. It is therefore recommended to individualize treatment based on the preferences and circumstances of each patient.

GCP: The treatment with glargine is not recommended in children with diabetes mellitus type 1, aged 6 years or less, since there is no evidence to compare glargine vs. NPH in this age group and there is already an effective and safe therapeutic alternative.

Pregnant Women

B: For the time being and waiting for new evidence on the safety of glargine, the use of NPH as basal insulin during pregnancy is recommended. Individually, its use could be considered in cases of significant worsening of metabolic control with NPH or in the presence of hypoglycaemias.

Detemir vs. Human Insulin

Adults

A: The use of detemir vs. NPH in adults with diabetes mellitus type 1 can be recommended, although the lack of data on long-term safety of this insulin should be noted.

Children and Adolescents

A: The widespread use of detemir cannot be recommended in children with diabetes mellitus type 1, although this therapy should be considered in children with nocturnal hypoglycaemia or threat thereof.

Glargine vs. Detemir

A: Both detemir and insulin glargine have similar effects in adults with diabetes mellitus type 1 in terms of metabolic control and hypoglycaemia, being insulin glargine that which can provide a higher quality of life for patients as detemir insulin should be administered in some cases twice a day.

Indications of the Continuous Subcutaneous Insulin Infusion Pump (Insulin Pump or CSII)

GCP: The treatment with continuous subcutaneous insulin infusion pump is not a universal option for all patients with diabetes mellitus type 1, as

candidates for this treatment must have a high level of diabetes education and have the support of a health team expert in this type of therapy. Therefore, to achieve greater profitability of the treatment, a proper selection of the candidate patients should be carried out, taking into account the metabolic control, the risk of acute complications acute and the higher cost.

A: The use of insulin pumps in patients with poor glycaemic control or disabling hypoglycaemia which have made invalid other conventional treatments (multiple dose insulin therapy) and which are able to achieve good adherence to the treatment, is recommended.

GCP: The HbA_{1c} level is not the only criterion to be considered when recommending the use of CSII treatment in pregnancy. This treatment option should be considered when a target less than 7% of HbA_{1c} level has not been achieved, after previously having optimized other aspects, integrating data from metabolic control, presence of difficult to manage hypoglycaemia, the quality of life of patients and the availability of the resource in the workplace.

Insulin Administration Methods in Patients with Diabetes Mellitus Type 1

Comparison of Pre-filled Pens

A: The use of pre-filled pens is recommended because they can encourage adherence to the treatment, but it will be the patient who decides on the administration system used.

Insulin Administration Techniques

Administration Site: Injection Site

B: In patients with diabetes mellitus type 1 fast-acting insulin injection is recommended in the abdomen in order to promote fast absorption, especially in cases of hyperglycaemic decompensation.

Rotation of Injection Points

A: Rotation in the insulin injection sites is recommended to prevent lipodystrophy.

A: It is recommended to change the insulin injections' area if the current site is affected by lipodystrophy, inflammation, edema or infection.

GCP: Patients should be taught a rotation scheme of the different injection sites.

GCP: It is recommended to divide the area into quadrants and change the quadrant clockwise weekly.

GCP: The injections in each quadrant are to be spaced at least 1 cm in order to avoid repetition of tissue trauma.

GCP: The clinician should verify in each visit that the rotation scheme is being followed and advice should be offered when needed.

Injection Technique (Injection Angle and Skin Fold)

GCP: It is important to consider the preferences of patients with diabetes mellitus type 1 when assessing the most appropriate injection technique as this aspect can improve adherence to the treatment.

C: The skin fold must be made by grasping the thumb and forefinger in a clamp.

B: In thin people, when the injection is performed on limbs or abdomen with 4-mm needles, it is advised not to use skin fold injecting perpendicularly in order to prevent potential intramuscular injections. If the needles are longer, it is advisable to inject with skin fold and at an angle of 45°.

B: In thin people, injections with 6-mm needles have to be performed properly with skin fold and at an angle of 45°.

B: Adult patients with diabetes mellitus type 1 using 8-mm needles or greater have to raise a skin fold or apply a tilt angle of 45º to avoid intramuscular injections.

A: In children and adolescents that use 6-mm needles, the injection is to be applied at an angle of 45° and with skin fold.

B: In children and adolescents that use 4-mm needles, the injection has to be applied at an inclination of 90°, without skin fold. For really thin people, skin fold may also be required.

GCP: If children or adolescents have only 8-mm needles (as is the case of those using syringes), the injection must be applied with skin fold and with an inclination of 45°.

Reusing Needles

GCP: It is recommended to change the needle at least every 3 or 4 uses, unless the user's skill allows using it more often without any pain.

Injection through the Clothes

A: Although not considered optimal practice since it does not allow the correct elevation of skin fold or to visualize the site of injection, injecting insulin through a layer of fabric is not ruled out in specific situations.

Needle Size

A: In adults with diabetes mellitus type 1, 4-, 5- and 6-mm needles can be used even by people who are obese and do not generally require skin fold, in particular when using 4-mm needles.

B: There is no medical reason to recommend needles longer than 8 mm. Initial therapy must begin with needles which are as short as possible.

A: Children and adolescents with diabetes mellitus type 1 have to use 4-, 5- or 6-mm needles. Thin people or people who are inject in a limb should lift a skin fold, especially when using needles that are longer than 4 mm.

B: There are no medical reasons to recommend needles which are longer than 6 mm in children and adolescents with diabetes mellitus type 1.

A: Children with normal weight using 8-mm needles must inject with skin fold and at an angle of 45°.

Indications for the Treatment with Metformin Added to Insulin in Adolescents with Diabetes Mellitus Type 1

GCP: The widespread use of metformin associated to the insulin treatment in adolescent patients, although its use in some patients may improve glycaemic control, cannot be recommended.

Pancreas and Islet Transplantation

B: Simultaneous transplantation of pancreas and kidney should be offered to young patients with diabetes mellitus type 1 (under 45), who are well informed and motivated, with end stage renal disease (ESRD) and without cardiovascular risk factors.

B: The criteria for isolated pancreatic transplantation are:

- Persistent failure in the insulin treatment in relation to glycaemic control and the prevention of complications
- Incapacitating clinical and emotional problems for insulin treatment

C: Nowadays, islet transplantation is only recommended in the context of controlled trials.

Management of Diabetes Mellitus Type 1 in Special Situations

Insulin Treatment Guidelines during Hospitalization of Patients with Diabetes Mellitus Type 1

Surgical Patient

A: The system of continuous intravenous infusions of insulin is the ideal method to achieve good metabolic control and prevent complications such as metabolic acidosis or hypoglycaemia in patients with diabetes mellitus type 1 who are to undergo major and minor surgery.

GCP: Hospitals should ensure the existence of an appropriate protocol for surgery in patients with insulin-dependent diabetes. This protocol must ensure the maintenance of normoglycaemia levels through frequent glucose measurements that allow the adjustment of intravenous (IV) insulin without the risk of acute complications.

Critical Patient

A: In the case of critical patients with persistent hyperglycaemia, the treatment must start with a threshold of no greater than 180 mg/dl (10 mmol/l). Once treatment has begun, glycaemic targets must be set in a range between 140 and 180 mg/dl (7.8 to 10 mmol/l) for the most critically ill patients.

GCP: It is necessary to establish a safe and effective protocol to achieve an adequate blood glucose range without an increase in severe hypoglycaemic episodes.

Stable Patient

GCP: All patients with diabetes admitted to a health center should have this diagnosis clearly identified in their medical history.

GCP: All patients with diabetes should have blood glucose levels monitored and this information should be available to the healthcare team.

B: Monitoring should be initiated in any known non-diabetic patient who is administered any treatment with a high risk of hyperglycaemia, including high doses of glucocorticoids, initiation of enteral or parenteral nutrition or other medications such as octreotide or immunosuppressives.

GCP: If hyperglycaemia is identified and persistent, treatment is needed. These patients should be treated with the same glycaemic targets as those applied for patients with known diabetes.

GCP: A hypoglycaemia treatment plan should be set out for each patient. All episodes of hypoglycaemia in the hospital should be registered.

GCP: All patients admitted to hospital have an HbA_{1c} level determination if data is not available for the 2-3 months prior to admission.

GCP: Patients with hyperglycaemia in the hospital with no prior accurate diagnosis of diabetes should have a protocol for diagnosis and monitoring of care at discharge.

Preventive and Treatment Measures in the Case of Outpatient Acute Intercurrent Diseases in Patients with Diabetes Mellitus Type 1

D: People with diabetes mellitus type 1 and/or their families or carers should be informed that intercurrent diseases could cause hyperglycaemia. They can also lead to ketosis and hypoglycaemia, the latter being more common in children under 6 years.

D: All people with diabetes mellitus type 1 and/or their families or carers have to be educated about disease management in case of intercurrent disease and should have at reach fast-acting insulin, glucose test strips, blood glucose test strips, lancets, strips and meters for the measurement of ketones in the blood or urine, refreshments/fruit juice/lemonade or other drinks alike, know how to use glucagon, a thermometer, paracetamol or ibuprofen, emergency guides or diabetes manuals and a contact telephone of their doctor or the hospital.

D: The administration of insulin should never be omitted, even if the patient is not able to eat.

D: Blood glucose and ketone bodies in urine (ketonuria) or blood (ketonemia) must be monitored frequently.

D: Any illness must be treated immediately.

D: Oral intake of extra liquids should be encouraged, especially if blood glucose is high or there are ketones.

D: Additional fast-acting insulin boluses should be provided in an amount, which is the same or greater than 10% to 20% of the total daily dose, every 2 to 4 hours if the blood glucose is high or ketones are present.

D: Patients/carers must immediately seek medical help if after the extra insulin boluses, blood glucose stays high, ketone bodies persist, nausea or vomiting or abdominal pain appear.

B: Small children may be administered small subcutaneous doses of glucagon to prevent or treat hypoglycaemia. For severe hypoglycaemia, intramuscular glucagon is recommended. Treatment with intravenous glucose should be performed within the hospital setting.

Psychological Disorders in Patients with Diabetes Mellitus Type 1

Affective and Anxiety Disorders

B: Professionals involved in the care of patients with diabetes mellitus type 1 should be alert to the possible emergence of depressive and/or anxious symptoms, especially when the person reports to have self-care problems.

GCP: Health professionals should have the necessary skills for the detection and management of non-severe forms of psychological disorders and be familiar with counseling techniques and the administration of psychotropic drugs.

GCP: Moderate to severe cases should be referred to mental health specialists.

Eating Disorders

C: The professional team members involved in the care of patients with diabetes mellitus type 1 should be alert about the possibility of occurrence of bulimia nervosa, anorexia nervosa and insulin management, especially in patients who express concern about their weight or body image, have a low body mass index (BMI) or poor glycaemic control.

D: Given the risk of increased morbidity and mortality associated with poor metabolic control in people with eating disorders, it is recommended

that in case of suspicion, the relevant diagnostic tasks are carried out and the department of psychiatry is contacted to apply the appropriate therapy.

B: Qualified health professionals should provide information on healthy lifestyles and particularly on diet regularly to patients with diabetes mellitus type 1, especially in the teenage years.

Risk of Decompensation of Diabetes Mellitus Type 1 during Adolescence

C: Adherence to the treatment is a key factor in managing diabetes, so it is important to work on this aspect with the adolescent patient together with his family, and analyze barriers, which may impede an adequate adhesion (anxiety, depression, eating disorders and behavioral problems).

C: The professionals in charge of children and adolescents with diabetes mellitus type 1 should be aware they might develop depression and/or anxiety disorders, particularly when there are difficulties in controlling the disease or if the disease is long lasting.

GCP: In children and adolescents with persistent poor glycaemic control, the level of anxiety and depression should be assessed.

GCP: Children and adolescents suspected to suffer anxiety or depression disorders should be referred to mental health professionals.

C: Given the high prevalence of eating disorders in adolescents with diabetes, especially among women, it is advised to be alert about the presence of symptoms that may indicate the presence of an eating disorder or insulin managing. In case of suspicion, the department of psychiatry for diagnosis and appropriate therapy should be contacted and worked with.

GCP: It is recommended to address the issue of alcohol, smoking and other drugs with the teenager with diabetes mellitus type 1 to avoid its consumption and provide strategies to prevent episodes of hypoglycaemia.

Pregnancy Planning

B: As all patients diagnosed with diabetes mellitus type 1, adolescents and women of childbearing age should participate in diabetes education programs in order to facilitate the control of their disease and promote self-care. These programs should include specific ideas about the importance of control before conception and general recommendations for pregnancy (vitamin supplements, suppression of teratogenic drugs, etc.). It is convenient to remind these patients about these points in all the visits to the health center to ensure a pregnancy in optimal conditions.

B: In women planning to become pregnant, it is considered relevant performing a pre-conceptional visit to set out control targets, establishing the appropriate treatment (folic acid, iodine, etc.), review the possible complications and give "green light" to the pregnancy.

Complications of Diabetes Mellitus Type 1 during Pregnancy

B: It is advisable to plan the pregnancy in women with diabetes mellitus type 1 to achieve adequate glycaemic control and conduct the evaluation of the possible retinopathy and nephropathy before and during pregnancy.

GCP: It is recommended to inform the couple on the mutual repercussions between diabetes mellitus type 1 and pregnancy, making explicit reference to the possible complications that can arise and the methods to prevent them.

Metabolic Control during Pregnancy

B: In pregnant women with diabetes mellitus type 1, individualized targets regarding the self-monitoring of blood glucose should be agreed on, taking into account the risk of hypoglycaemia. HbA_{1c} levels must be maintained below 6.2%, if these can be reached safely.

B: These women should be informed that any decrease in HbA_{1c} levels below 6.2% reduces the risk of congenital malformations and likewise, they should be recommended not to exceed levels higher than 6.9%.

B: Pregnancy should be discouraged to pregnant women with diabetes mellitus type 1 whose HbA_{1c} levels are above 8% on a temporary basis until an optimal metabolic control is achieved.

D: Situations that make pregnancy inadvisable:

- HbA_{1c} levels over 8%
- Severe nephropathy (plasma creatinine >2 mg/dl or proteinuria >3 g/24 hours and/or difficult to control arterial hypertension)
- Ischemic cardiopathology
- Severe proliferative retinopathy, with poor visual prognosis
- Severe autonomic neuropathy

GCP: Information is to be provided to the future pregnant woman and her partner on the need, first, to assess the situation of maternal diabetes to detect possible contraindications of gestation and, secondly, to express the desirability of an active participation of both to achieving the pre-conception objectives.

B: Monthly or bimonthly measurements of HbA_{1c} should be offered to women who are planning pregnancy.

B: Women who are planning pregnancy and require intensification of insulin therapy should be informed of the need to increase the frequency of self-analysis of blood glucose control including fasting and pre and postprandial controls. If necessary, the continuous insulin infusion pump therapy will be offered.

GCP: Test strips for self-assessment of ketonuria or ketonemia if hyperglycaemia appears or the person is feeling bad are to be provided.

GCP: Care to the patient with diabetes mellitus type 1 during pregnancy planning, monitoring and delivery should be in a hospital that has staff dedicated specifically to these aspects (nurse educator, endocrinologist, obstetrician, and neonatologist).

GCP: During pregnancy, the frequency of visits should be at least on a monthly basis, with both endocrinology and obstetrics specialists.

GCP: Since it is recommended to assess HbA_{1c} levels monthly, it would be advisable to do it through a capillary sample and not a venous one.

GCP: An increase in the use of test strips for blood glucose, ketonuria and/or ketonemia measurements should be taken into consideration.

GCP: Glycaemic control optimization protocols should be available.

GCP: A childbirth care protocol with general guidelines on the needs of carbohydrate intake and insulin, which must be known by the staff involved, as well as a newborn care protocol should be set out.

Contraception and Diabetes Mellitus Type 1

D: Women with type 1 diabetes are recommended to use the copper intrauterine device (IUD) as safest contraception method. The use of the IUD that releases levonorgestrel (LNG) cannot be ruled out, as it has not been observed to affect the metabolism of glucose.

Clinical Management of Diabetes Mellitus Type 1 in Patients with Special Needs

Immigrant Population. General Recommendations

GCP: If the patient with diabetes mellitus type 1 presents with difficulties understanding the language, the use of automatic translation systems (via telephone or audiovisual methods of open and closed questions) or by direct translation during the visit is recommended.

GCP: Likewise, the use of simple graphics that facilitate understanding of the disease and the guidelines to be followed is recommendable.

Recommendations for Muslim Patients during Ramadan

Before Ramadan

GCP: Inform the health care team about the concept of Ramadan and the risks posed by fasting.

GCP: Plan the process in time for the celebration of Ramadan.

GCP: Identify Muslim patients with diabetes mellitus type 1.

GCP: Carry out a clinical interview with these patients to know their desire to fulfill the precept of Ramadan.

GCP: Inform patients about the possibility of not celebrating Ramadan due to having a chronic disease and the risks involved.

GCP: Evaluate the existence of major criteria to strongly discourage compliance of Ramadan:

- Diabetes with poor metabolic control
- Chronic complications of advanced diabetes: renal failure, ischemic heart disease with unstable angor, advanced peripheral macroangiopathy
- Frequent hypoglycaemia, severe or without adrenergic clinic
- Diabetic ketoacidosis in the months prior to Ramadan
- Gestation
- Physical activity during the day
- Aged with dependence on others

GCP: In the event that these criteria are not met and the patient wishes to fulfill the precepts, making the corresponding therapeutic changes before and during Ramadan regarding diet and exercise is deemed appropriate:

- Optimize glycaemic and metabolic control 1 to 2 months before
- Specific diabetes education (symptoms of hyper-and hypoglycaemia, meal and physical activity planning, drug administration and attitude in case complications arise)

During Ramadan

GCP: Individualized care plan

GCP: Frequent blood glucose determinations

GCP: Avoid foods which are rich in carbohydrates with rapid absorption and fats.

GCP: Eat more foods composed of complex carbohydrates.

GCP: Fruits, vegetables and yogurt can be included in the diet.

GCP: Practicing suhoor immediately before sunrise and not in the early morning.

GCP: Drink unsweetened fluids to quench thirst.

GCP: Reduce fried foods.

GCP: Carry out regular physical activity, avoiding excessive exercise.

GCP: Break fasting if blood glucose is less than 60 or higher than 300 mg/dl.

GCP: Ensure adequate fluid intake.

A: Adapt drug treatment with insulin: as a general rule, a basal bolus therapy, which eliminates the bolus of meals not taken, is recommended.

Patients with Visual Impairment

GCP: Provide educational materials in audio, Braille, large print or edited format.

GCP: Facilitate attendance to educational sessions performing them in locations accessible by public transport.

GCP: Advertise informative talks with brief advertisements in audio format.

GCP: If slides are used to transmit key information at educational chats, these should also contain a simple verbal description of the contents of each slide.

GCP: Provide information on self-control tools and techniques for people with visual impairment, including:

- "Talking blood glucose monitoring kits" that guide the patient through a voice message on the steps for testing and communicate the results orally
- Glucometers with a large screen and easily recognizable numbers
- Glucometers with backlit display
- Techniques for tactile inspection of the feet

GCP: Insulin injectors:

- Provide patients with injectors, which contain different touch buttons for fast or slow insulin.
- Insulin injectors emit some sort of sound when going from dose to dose in order to facilitate the patient's autonomy, and thus the dose can be calculated without seeing the wheel.

Acute Complications

Hypoglycaemia

Symptoms of Suspicion

<table>
<tr><td></td><td colspan="4">Hypoglycaemia will be suspected in the presence of one or more of the following symptoms:

Symptoms of Hypoglycaemia</td></tr>
<tr><td rowspan="3">D</td><td colspan="2">Autonomic/Adrenergic/Neurogenic</td><td colspan="2">Neurological/Neuroglycopenic</td></tr>
<tr><td>• Sweating
• Paleness
• Trembling
• Tachycardia</td><td>• Anxiety
• Hunger
• Nausea
• Weakness
• Tingle</td><td>Psychiatric symptoms:
• Confusion
• Behavioural alteration
• Aggressiveness
• Slurred speech
• Lapses of consciousness</td><td>Neurological symptoms:
• Dizziness and weakness
• Headache
• Altered, double or blurred vision
• Aphasia
• Dysarthria
• Motor deficit, unsteady gait, lack of coordination
• Paresthesias
• Seizures</td></tr>
<tr><td colspan="4">*Adapted from hypoglycaemia for the Reversal Treatment of Mild, Moderate and Severe. Holders of Interdisciplinary Clinical Manual CC15-25.</td></tr>
<tr><td>GCP</td><td colspan="4">It is recommended that people with diabetes type 1, especially children and young people, carry identification (e.g., bracelet) to facilitate the identification of acute complications such as hypoglycaemia and acting at an early stage.</td></tr>
</table>

Criteria for Evaluating the Severity

GCP: Small children with diabetes mellitus type 1 always require adult assistance to solve hypoglycaemia. The severity of hypoglycaemia is established exclusively based on the symptomatology.

Performance Measures in Case of Hypoglycaemia

Mild or Moderate Hypoglycaemia (see Appendix 8.1 in the original guideline document)

A: Mild or moderate hypoglycaemia needs to be treated by oral ingestion of 10 to 20 g of carbohydrates, preferably in the form of glucose tablets or solutions, sugar or sucrose. These are preferred to fruit juices or glucose gels. Examples of options containing 15 g of carbohydrates:

- 15 g of glucose in tablets
- 15 g of sugar dissolved in water (3 teaspoons with sugar or 3 lumps of sugar)
- 175 ml (3/4 cup) of juice or sugary drink
- 15 g (1 tablespoon) of honey

GCP: Following the administration of oral carbohydrates, the patients or family caregivers must wait 10 to 20 minutes, measure the blood glucose levels again and repeat the intake of carbohydrates if the glucose level is less than 72 mg/dl (4.0 mmol/l).

Severe Hypoglycaemia (see Appendix 8.2 in the original guideline document)

GCP: Severe hypoglycaemia in a conscious person must be treated by oral ingestion of 10 to 20 g of carbohydrates, preferably in the form of glucose tablets or equivalent. One must wait 15 minutes, measure the blood glucose levels again and repeat the intake of another 15 g of carbohydrates if the glucose level is less than 4.0 mmol/l (72 mg/dl).

GCP: Severe hypoglycaemia in an unconscious person over 5 years old, if diagnosed at home, should be treated with 1 mg of subcutaneously or intramuscularly injected glucagon. If it is a child under 5 years old, 1/2 mg of subcutaneously injected glucagon should be administered. When it is possible to inject intravenously, it should be administered from 10 g to 25 g of glucose (20 cc to 50 cc of dextrose at 50%) for 1 to 3 minutes.

GCP: Caregivers or support people for patients at risk of severe hypoglycaemia should be trained in the administration of injected glucagon.

GCP: To prevent hypoglycaemia, once the episode has been overcome, the person should eat regular food that corresponds to that time of day. If the next meal is to take place more than an hour later, it is advisable to eat a snack that contains 15 g of carbohydrates and a source of protein.

Chronic Complications

Cardiovascular Risk in Patients with Diabetes Mellitus Type 1

B: The use of arterial risk clinical prediction rules is not recommended in adult patients with diabetes mellitus type 1, as these may underestimate their cardiovascular risk.

GCP: An individualized evaluation of the cardiovascular risk of patients with diabetes mellitus type 1 based on the presence or absence of risk factors such as age, gender, duration of the disease, glycated haemoglobin levels, blood pressure, smoking or low-density lipoprotein (LDL) levels is recommended.

GCP: The evaluation of arterial risk factors should be made at least annually and include:

- Age
- Evolution of the disease
- Family history of vascular disease
- Smoking habits
- Albumin excretion ratio
- Blood glucose control
- Blood pressure
- Complete lipid profile (including high-density lipoprotein [HDL] cholesterol, LDL-cholesterol and triglycerides)
- Abdominal adiposity

GCP: Adults with a high rate of albumin excretion (microalbumin) or two or more features of the metabolic syndrome should be managed as high-risk category.

GCP: Adults with diabetes mellitus type 1 who are not in the category of higher risk but have some arterial risk factor (over 35 years old, family history of premature coronary disease, high-risk ethnicity, or severe lipidemia or blood pressure alterations) should be managed as a moderately high risk group.

Diabetic Retinopathy

A: It is important to inform people with diabetes mellitus type 1 and their families that the control of long-term blood glucose with HbA_{1c} levels lower or equal to 7% decreases the incidence and progression of diabetic retinopathy.

Diabetic Retinopathy Screening Techniques

B: The retinal digital photography obtained by non-mydriatic camera should be implemented in retinopathy screening programs for adults and children with diabetes mellitus type 1.

B: Should a camera not be available, screening will be carried out through an ophthalmoscopy (with or without mydriasis), which will be evaluated by an ophthalmologist.

GCP: The use of retinal digital photography obtained electronically by a non-mydriatic camera facilitates the screening performance for both the patient and the health staff.

GCP: Although retinal digital photography may detect many clinically significant alterations, digital photographs of the retina should not replace the full initial examination and with mydriasis of the retina.

Start Time and Frequency of Screening for Diabetic Retinopathy

B: In people with diabetes mellitus type 1, it is recommended to start screening for retinopathy after puberty, or after 5 years since the diagnosis of diabetes.

B: If retinopathy is detected, it is considered advisable to perform a screening for retinopathy once a year.

B: Should retinopathy not be detected in the baseline examination of the retina, it is recommended to perform a retinopathy screening every 2 or 3 years.

Diabetic Nephropathy

Criteria for Referral of Patients with Diabetic Nephropathy to Specialized Care Nephrology Units

D: It is recommended to refer to specialized care units in nephrology those patients with diabetes mellitus type 1 who have at least one of the following criteria:

1. With glomerular filtration > 45 ml/min/1.73 m^2 of body surface area:
    - Increasing albuminuria or albuminuria/creatinine ratio >300 mg/g
    - Incorrected anaemia (haemoglobin [Hb] <11g/dl) despite iron treatment
    - Refractory hypertension (3 drugs)
2. With glomerular filtration 30-45 ml/min/1.73 m^2 of body surface area:
    - Individual assessment, taking into account the age and rate of progression or of kidney failure, provided that it meets the criteria above regarding proteinuria, anaemia and refractory hypertension
3. With glomerular filtration <30 ml/min/1. 73 m^2 of body surface area:
    - In all cases

Preferred referral criteria:

- Fast increase of serum creatinine: >1 mg/dl in a month.
- Hematuria associated to proteinuria once urological diseases are discarded through renal ultrasound scan.
- Severe hyperkalaemia (>7 mEq/l).

Treatment of Patients with Diabetes Mellitus Type 1 and Microalbuminuria

A: The pharmacological treatment of choice in hypertensive and normotensive patients with microalbuminuria is an angiotensin converting enzyme inhibitor (captopril, lisinopril, ramipril, enalapril and perindopril) with a progressive increase in the therapeutic dose to achieve the desired response.

A: During pregnancy and in the case of existing renal artery bilateral stenosis, the treatment with angiotensin converting enzyme inhibitor drugs is contraindicated.

GCP: During the treatment with an inhibitor of angiotensin converting enzyme, the levels of creatinine and potassium should be monitored.

GCP: If there is a contraindication or intolerance to the angiotensin converting enzyme inhibitors, a treatment with angiotensin II receptor antagonists is recommended.

GCP: The goals of treatment are to control blood pressure and reduce the urinary albumin excretion. In normotensive patients, the dose administered will be the maximum tolerated.

Frequency of Screening for Diabetic Nephropathy

B: The measurement of the albumin/creatinine ratio in a sample of first morning urine is recommended as a method for the detection and monitoring of diabetic nephropathy.

D: Five years after the diagnosis of diabetes mellitus type 1, an annual screening of the nephropathy is recommended.

Diabetic Foot

A: It is recommended that patients with diabetes mellitus type 1 are involved in structured screening, risk stratification, and prevention and treatment of the foot at risk programs.

GCP: Diabetic foot screening in people with diabetes mellitus type 1 should begin after 5 years of progression of the disease as from puberty.

D: A module on foot care education should be included in consonance with the risk assessment.

B: Diabetic foot screening should include a thorough annual examination of the feet to identify risk factors, prediction of ulcers and amputations; inspection of the foot and soft tissue; assessment of footwear; musculoskeletal examination; assessment of peripheral arterial disease symptoms using an evaluation of the foot pulses, supplemented by the determination of the ankle-arm index, in some cases; and the loss of sensitivity tests assessed by monofilament or alternatively by the turning fork.

D: Three levels of monitoring are recommended depending on the risk factor of patients:

Risk (Classification)	Features	Inspection Frequency
Low risk	Preserved sensitivity, palpable pulses	Annual
Increased risk	Neuropathy, absence of pulses and other risk factors	Every 3-6 months (with control visits)
High risk	Neuropathy or absent pulses together with deformity or skin changes or prior ulcers	Every 1-3 months
Ulcerated foot		Individualized treatment, possible referral

GCP: Since diabetes is the most frequent cause of non-traumatic amputation of lower limbs, it is desirable to standardize the process of education and prevention, diagnosis and treatment of diabetic foot, in a multidisciplinary way, with the aim of reducing the number of amputations and comorbidity involved.

Erectile Dysfunction in People with Diabetes Mellitus Type 1

A: The treatment with phosphodiesterase inhibitors is recommended as first choice for the treatment of erectile dysfunction in people with type 1 diabetes.

A: In case of contraindication or poor tolerance, intracavernosal alprostadil is proposed as an alternative.

B: As a third option treatment, mechanical methods can be considered, such as vacuum devices and inflatable prosthesis (in this order).

A: In case all previous methods fail, sublingual apomorphine treatment can be considered.

Painful Diabetic Neuropathy

GCP: As first line of treatment for mild cases, analgesics such as acetaminophen or ibuprofen or paracetamol or aspirin, as well as treatments of local use such as the arch, to isolate the foot are recommended.

A: When these measures fail, the use of tricyclic drugs (low to medium dose) is recommended, taken just before the time of day when the symptoms are more annoying. The diabetic patient must be informed about the type of trial, as it is not always successful.

A: When the response to treatment is insufficient, drugs may be associated with different mechanisms of action, such as antiepileptics (gabapentin or pregabalin), opioids (such as morphine, oxycodone, or tramadol) or duloxetine, monitoring the response and the adverse effects.

Organizing the Medical Consultation

Transition of Patients with Diabetes Mellitus Type 1 from Paediatric Services to the Adult Services

C: Set up at least one consultation visit involving both the paediatrician who has been responsible for the treatment during childhood and the endocrinology specialist who will attend the patient with diabetes mellitus type 1 in the future is recommended, so that they agree and fix the treatment together with the adolescent.

Initial Study of the Newly Diagnosed Patients with Diabetes Mellitus Type 1

In the newly diagnosed diabetes mellitus type 1 patients, the following assessments are recommended:

Medical History

GCP:

- Domestic, social, cultural-recreational aspects, level of education
- Emotional situation
- Assessment of family and social support
- Prior diabetic history
- Vascular risk factors
- Smoking
- Family history of diabetes and artery or autoimmune disease

General Exploration

GCP: Height, weight, BMI, blood pressure

Further Tests

- A: HbA_{1c}
- B: Full examination of the retina with mydriasis
- B: Albumin excretion (timed microalbuminuria or albumin/creatinine ratio)
- GCP: Lipid profile once the glycaemic profile is stabilized
- B: Anti-thyroid peroxidase antibodies (TPO), free thyroxine (FT4) and thyroid-stimulating hormone (TSH) antibodies
- B: Transglutaminase and immunoglobulin A (IgA) antibodies to assess celiac disease
- D: Regular measuring of the C-peptide or specific autoantibodies or to confirm the diagnosis of diabetes mellitus type 1 is not advised, but its use should be considered to determine the etiology of diabetes mellitus in doubtful cases.
- B: Testing for autoimmune thyroid disease and celiac disease in the early onset of diabetes mellitus type 1 in children and adolescents is not recommended.

Genetic Study

- D: In cases in which mild sustained hyperglycaemia is identified in a young person, without obesity and/or mild diabetes history in two generations, in the absence of anti-pancreatic autoimmunity and HLA not compatible with diabetes mellitus type 1, MODY 2 diabetes should be ruled out.
- D: If hyperglycaemia is more severe and progressive, MODY 3 diabetes should be ruled out.
- D: If genetic testing is negative for MODY 2 and MODY 3 diabetes, then the rest of MODY varieties should be ruled out too.

Educational and Support Materials

B (Adults)/A (Children): Updated information should be provided to the adults, children and adolescents with diabetes mellitus type 1 together with their families at the time of diagnosis, and periodically thereafter, on the existence of diabetic support groups, both locally and nationally and how to contact them (see Appendix 11.2 in the original guideline document).

Follow-up and Control Consultations: Tests and Frequency

GCP: It is recommended to design an individualized care plan, which should be reviewed annually to adjust to the desires, personal circumstances and medical findings of each patient. The specific details of this individual plan must be registered in writing and include aspects related to:

- Diabetes education, including dietary advice
- Insulin
- Self-assessment and management of blood glucose (insulin dose modification, mild and severe hypoglycaemia and awareness of it and hyperglycaemia ketosis)
- Assessment and management of late complications, including foot exam
- Assessment and management of arterial risk factors
- Psychosocial problems and dental disease
- Frequency of communication with the professional team
- Further consultation planned, including the next annual review

Strength of Recommendation	Periodic Reviews	Children and Young People	Adults
D	Glycosylated haemoglobin (HbA_{1c})	From 3 to 4 times a year or more regularly if there is a concern about poor glycaemic control.	
C	Inspection of injection sites	In each visit.	
GCP	Measurement of height, weight and calculation	In each visit in a private room.	The same with the exception of size in adults.

Strength of Recommendation	Periodic Reviews	Children and Young People	Adults
	of body mass index (BMI)		
GCP	Blood pressure	Annually	In each visit.
GCP	Complete lipid profile	Annually after the age 12.	Annually
GCP	Abdominal circumference	—	Annually
GCP	Smoking	Annually from adolescence.	Annually
GCP	Family history of arterial disease	—	Annually
D	Eye exam	As the general population.	Visual acuity every 2-3 years.
D	Dental exam	As the general population.	
GCP	Nephropathy	Annual measuring of the albumin/creatinine ratio in a sample first thing in the morning 5 years after the evolution of the disease is recommended.	
B	Arterial risk	Arterial risk tables, equations or calculation programs are not recommended because arterial risk calculation programs may underestimate the risk in adults with diabetes mellitus type 1. Individual assessment is recommended depending on the presence or absence of risk factors.	
B	Retinopathy	If there is no retinopathy or it is mild, it is recommended to carry out screening every 2-3 years after puberty or after 5 years of evolution. If there is retinopathy, it is recommended to assess the evolution once a year.	
GCP	Rating autoimmune thyroid disease and celiac disease	Every two years for the first 10 years of the disease progression and then every five years.	

Definitions:

Levels of Evidence: Scottish Intercollegiate Guidelines Network (SIGN)

1++	High quality meta-analyses, systematic reviews of clinical trials or high-quality clinical trials with very little risk of bias.
1+	Well-conducted meta-analyses, systematic reviews of clinical trials, or well-conducted clinical trials with low risk of bias.
1-	Meta-analyses, systematic reviews of clinical trials or clinical trials with high risk of bias.
2++	High-quality systematic reviews of case-control or cohort studies. Cohort or case-control studies with very low risk of bias and with high probability of establishing a causal relationship.
2+	Well-conducted case-control or cohort studies with low risk of bias and a moderate probability of establishing a causal relationship.
2-	Case-control or cohort studies with a high risk of bias and a significant risk that the relationship is not causal.
3	Non-analytical studies such as case reports and case series.
4	Expert opinion.

Note: Studies classified as 1- and 2- should not be used in the process of developing recommendations due to their high potential for bias.

Levels of Evidence for Diagnosis-related Questions

National Institute for Health and Care Excellence (NICE) adaptation of the levels of evidence of the Oxford Centre for Evidence-Based Medicine and the Centre for Reviews and Dissemination

Levels of Scientific Evidence	Type of Scientific Evidence
Ia	Systematic review with homogeneity of level 1 studies
Ib	Level 1 studies
II	Level 2 studies Systematic review of level 2 studies
III	Level 3 studies Systematic review of level 3 studies
IV	Consensus, expert opinion without explicit critical appraisal
Level 1 Studies	Meet: • Masked comparison with a valid reference test ("gold standard") • Adequate spectrum of patients
Level 2 Studies	They have only one of these biases: • Non-representative population (the sample does not reflect the population where the test will be applied) • Comparison with the inadequate reference standard ("gold standard") (the test will be evaluated as part of the gold standard or the result of the test result affects the implementation of the gold standard) • Comparison is not masked • Case-control studies
Level 3 Studies	Meet two or more of the criteria described in level 2 studies

Grades of Recommendation for Intervention Studies: Scottish Intercollegiate Guidelines Network (SIGN)

A	At least one meta-analysis, systematic review or clinical trial rated as 1++ and directly applicable to the target population of the guideline, or body of scientific evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.
B	A body of scientific evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1 +.
C	A body of scientific evidence consisting of studies rated as 2+, directly applicable to the target population of the guideline and overall consistency of results; or evidence extrapolated from studies classified as 2++.
D	Scientific evidence level 3 or 4, or extrapolated evidence from studies rated as 2 +.
Good Clinical Practice (GCP)*	Recommended practice based on clinical experience and the consensus of the editorial team.

*Sometimes the development group realises that there are some important practical aspects, which should be emphasised, and for which there is probably no scientific evidence that supports them. In general, these cases are related to some treatment aspect considered to be "good clinical practice" and usually no one would argue about them. These aspects are rated as points of good clinical practice.

Grades of Recommendation for Diagnosis-Related Questions

Recommendation	Evidence

Recommendation	Evidence
A	Ia or Ib
B	II
C	III
D	IV

Clinical Algorithm(s)

The following algorithms are provided in the appendices of original guideline document:

- Treatment of mild hypoglycaemia
- Treatment of severe hypoglycaemia

Scope

Disease/Condition(s)

Diabetes mellitus type 1

Other Disease/Condition(s) Addressed

- Anxiety
- Depression
- Eating disorders
- Erectile dysfunction
- Nephropathy

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Internal Medicine

Medical Genetics

Nephrology

Neurology

Nursing

Nutrition

Obstetrics and Gynecology

Ophthalmology

Optometry

Pediatrics

Podiatry

Preventive Medicine

Psychiatry

Psychology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Nurses

Optometrists

Other

Patients

Pharmacists

Physician Assistants

Physicians

Podiatrists

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Guideline Objective(s)

- To improve the quality, efficiency and equity of care for people with diabetes mellitus type 1 (DM1) in the Spanish National Health System
- To provide guidance on the various alternatives for the care provided to people with DM1, establishing the most relevant and up-to-date evidence-based recommendations
- To develop standards that can maximize the quality, efficiency and equity of care for people with DM1
- To help patients make informed decisions to facilitate self-care

Target Population

Children, adolescents and adults (including pregnant women) with diabetes mellitus type 1, assisted in primary and specialty care, both in the intra- and outpatient means within the Spanish National Health System

Interventions and Practices Considered

Diagnosis/Evaluation/Counseling

1. Use of autoantibodies in the diagnosis of diabetes mellitus type 1
2. Assessment of predictors of 'spontaneous remission'
3. Genetic studies to rule out maturity onset diabetes of the young (MODY) diabetes
4. Study of antibodies to rule out other autoimmune multiglandular diseases
5. Diabetes education for patients and families
6. Community support arrangement

Treatment/Management/Prevention

1. Diet specifications, including diet for prevention of cardiovascular disease
2. Eating plans
3. Exercise, including type, intensity, and duration
4. Glycaemic control (establishing glycosylated haemoglobin [HbA_{1c}] targets)
5. Continuous glucose monitoring
6. Inpatient versus outpatient clinical management
7. Choice of insulin preparations (fast-acting analogues, slow-acting analogues, human insulin)
8. Use of continuous subcutaneous insulin infusion (CSII) pumps
9. Methods of insulin administration (disposable syringes, prefilled pens)
10. Insulin administration techniques (injection sites, injection angles, skin folds, needle sizes)
11. Adding metformin to insulin
12. Pancreas and islet transplantation
13. Management of diabetes mellitus type 1 in special situations
    - Hospitalized patients
    - Acute intercurrent diseases
    - Psychological disorders
    - Decompensation during adolescence
    - Pregnancy planning
    - Management during pregnancy
    - Contraception choice
    - Management of patients with special needs (immigrant populations, patients with visual impairment)
14. Management of acute complications (mild, moderate, severe hypoglycaemia)
15. Management of chronic complications
    - Management of cardiovascular risk
    - Screening for and prevention of diabetic retinopathy
    - Screening for and treatment of diabetic nephropathy
    - Screening for diabetic foot
    - Treatment of erectile dysfunction
    - Treatment of painful diabetic neuropathy
16. Organizing the medical consultation

- Transition of patient from paediatric to adult services
- Initial study of the newly diagnosed patient
- Follow-up consultations: tests and frequency

Major Outcomes Considered

- Validity and diagnostic value of C-peptide and specific antibodies for confirmation of diabetes mellitus type 1
- Spontaneous remission
- Hypoglycaemic events
- Glycaemic control
- Morbidity
- Mortality
- Cardiovascular risk
- Complications in pregnancy and childbirth
- Diabetic retinopathy, nephropathy, neuropathy, and other complications associated with diabetes
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Bibliographic Search

There has been a search for clinical practice guidelines (CPG) to identify the latest and of highest quality and clinical studies to identify the highest quality evidence available.

CPG Search

Search period from 1998 to March 2011. Languages: Spanish, English, French and German.

The following were consulted:

- Agencies databases from collector bodies:
  - Trip database (European, American and English guides)
  - NeLH (National Electronic Library of Health, United Kingdom)
  - Canadian Medical Association
  - GuíaSalud (Clinical Practice Guidelines in the National Health System)
- Databases from developing bodies:
  - NICE (National Institute for Health and Care Excellence in the UK)
  - SIGN (Scottish Intercollegiate Guidelines Network)
  - FISTERRA Atención Primaria en la Red
  - NGC (National Guideline Clearinghouse, U.S.)

A search of medicine databases based on evidence and general databases was also performed: MEDLINE (PubMed) and EMBASE (Elsevier).

Search for Research Studies

Search period: from 2003 to March 2011 (including warnings) for updated questions from the NICE CPG 2004. For the questions about pregnancy, which were based on the NICE CPG 2008, the search term was from 2007 to 2011 (including warnings).

After the identification and selection of a CPG, a specific research was carried out on studies for each clinical question in Cochrane Library Plus and the database of the National Health Service (NHS) Center for Reviews and Dissemination, which in turn includes the HTA database (Health Technology Assessment) on assessment reports and the DARE base of reviews of effectiveness. General databases such as MEDLINE (PubMed) and EMBASE (Elsevier) were also used.

The whole process was completed using a general Internet search (scientific organizations and societies) and reverse look up in articles from the most relevant studies to locate other relevant information.

The bibliographic search strategies are included in the document "Methodological material" available on the GuíaSalud website: http://portal.guiasalud.es/emanuales/elaboracion/index-02.html .

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence: Scottish Intercollegiate Guidelines Network (SIGN)

1++	High quality meta-analyses, systematic reviews of clinical trials or high-quality clinical trials with very little risk of bias.
1+	Well-conducted meta-analyses, systematic reviews of clinical trials, or well-conducted clinical trials with low risk of bias.
1-	Meta-analyses, systematic reviews of clinical trials or clinical trials with high risk of bias.
2++	High-quality systematic reviews of case-control or cohort studies. Cohort or case-control studies with very low risk of bias and with high probability of establishing a causal relationship.
2+	Well-conducted case-control or cohort studies with low risk of bias and a moderate probability of establishing a causal relationship.
2-	Case-control or cohort studies with a high risk of bias and a significant risk that the relationship is not causal.
3	Non-analytical studies such as case reports and case series.
4	Expert opinion.

Note: Studies classified as 1- and 2- should not be used in the process of developing recommendations due to their high potential for bias.

Levels of Evidence for Diagnosis-related Questions

National Institute for Health and Care Excellence (NICE) adaptation of the levels of evidence of the Oxford Centre for Evidence-Based Medicine and the Centre for Reviews and Dissemination

Levels of Scientific Evidence	Type of Scientific Evidence
Ia	Systematic review with homogeneity of level 1 studies
Ib	Level 1 studies
II	Level 2 studies Systematic review of level 2 studies

III Levels of Scientific Evidence	Level 3 studies Type of Scientific Evidence Systematic review of level 3 studies
IV Evidence	Consensus, expert opinion without explicit critical appraisal
Level 1 Studies	Meet: • Masked comparison with a valid reference test ("gold standard") • Adequate spectrum of patients
Level 2 Studies	They have only one of these biases: • Non-representative population (the sample does not reflect the population where the test will be applied) • Comparison with the inadequate reference standard ("gold standard") (the test will be evaluated as part of the gold standard or the result of the test result affects the implementation of the gold standard) • Comparison is not masked • Case-control studies
Level 3 Studies	Meet two or more of the criteria described in level 2 studies

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Assessment of the Methodological Quality

The methodological quality of the clinical practice guidelines (CPGs) found by the Appraisal of Guidelines for Research & Evaluation (AGREE) instrument was assessed, and the National Institute for Health and Care Excellence (NICE) CPG 2004 was selected for having the highest score. It was considered a reference CPG for its update/adaptation according to the methods proposed by the document "Descripción de la metodología de elaboración-adaptación-actualización empleada en la Práctica Clínica sobre Asma en la CAPV" (Description of the development – adaptation – update methodology used in the Clinical Practice on Asthma within the Basque Autonomous Community) (see the "Availability of Companion Documents" field).

For those questions that were not addressed by this guide, a new search on research studies was carried out and the system proposed by the Scottish Intercollegiate Guidelines Network (SIGN) for assessing the methodological quality of the studies was used.

Data Extraction

Performed by two independent reviewers.

Development of Evidence Tables

The evidence tables are included in the document "Methodological material" available in the website of GuíaSalud: http://portal.guiasalud.es/emanuales/elaboracion/index-02.html.

Classification of Studies and Grades of Recommendations

For the classification of levels of evidence and grades of recommendations, the SIGN scale was used for questions about effectiveness and safety of interventions or treatments and the Oxford classification for the diagnostic questions (see the "Rating Scheme for the Strength of the Evidence" and "Rating Scheme for the Strength of the Recommendations" fields).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

This clinical practice guideline (CPG) has been created following the Methodological Manual "Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud" (Development of Clinical Practice Guidelines in the National Health System [NHS]) and the document "Descripción de la metodología de elaboración-adaptación-actualización empleada en la Práctica Clínica sobre Asma en la CAPV" (Description of the development – adaptation – update methodology used in the Clinical Practice on Asthma within the Basque Autonomous Community) which can be consulted on the website of the Library of CPG of the NHS, GuíaSalud (see the "Availability of Companion Documents" field).

During the development process of this CPG, a mixed methodology has been applied, using a strategy of renovation and adaptation to the questions that are answered in the CPG "Type 1 diabetes: diagnosis and management of type 1 diabetes in children, young people and adults 2004" from the National Institute for Health and Care Excellence (NICE) published in 2004 (CPG NICE 2004) previously selected by the Appraisal of Guidelines for Research & Evaluation (AGREE) instrument for its highest quality.

To address those questions that are not answered in the aforementioned guide the "de novo" development process has been followed.

For questions, regarding pregnant women with diabetes mellitus type 1, the upgrading and adaptation process has been made from the CPG "Diabetes in pregnancy management of diabetes and its complications from preconception to the postnatal period. National Collaborating Center for Women's and Children's Health Commissioned by the National Institute for Health and Care Excellence 2008" by NICE (NICE CPG 2008).

For questions 11.1 and 11.4 in the original guideline document, the upgrading process has been carried out from the diabetes CPG on diabetes type 2 of the Spanish NHS.

The steps that taken during the preparation of the CPG were as follows:

Constitution of the Guide Development Team

Diabetes mellitus type 1 specialty care professionals (endocrinologists, pediatric endocrinologists and diabetes nurse educators) with proven expertise, experienced professionals in the development of CPG and evidence-based medicine, as well as experts on scientific literature and systematic revisions have collaborated in the development of this CPG. Likewise, people with diabetes mellitus type 1 and carers have participated and contributed in various stages of the development process (defining the scope and focus of the CPG, formulating research questions, developing and reviewing the recommendations).

Formulation of Clinical Questions

It has been carried out using the PICO format: P (patients), I (interventions), C (comparisons) and O (outcomes or results). For proper formulation, a training workshop was provided previously for people involved in this process (doctors and nurses in diabetes mellitus type 1, experts in systematic reviews, people with diabetes mellitus type 1 and caregivers).

Edition of the Guide

Throughout this CPG there are recommendations based on publications of 'consensus or expert opinion' qualified with the letter "D". The symbol '√' is used in the original guideline document (Good Clinical Practice [GCP] in this summary) to define 'consensus of the development team'. This last grade of recommendation is used in cases where there are no publications or when despite having studies, evidence must be adapted due to the context of application. Along the document, the information provided by studies about the type and level of evidence reflecting the possibility of bias in the literature reviewed is presented.

Rating Scheme for the Strength of the Recommendations

Grades of Recommendation for Intervention Studies: Scottish Intercollegiate Guidelines Network (SIGN)

A	At least one meta-analysis, systematic review or clinical trial rated as 1++ and directly applicable to the target population of the guideline, or body of scientific evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.
B	A body of scientific evidence including studies rated as 2++, directly applicable to the target population, and demonstrating

	overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1 +.
C	A body of scientific evidence consisting of studies rated as 2+, directly applicable to the target population of the guideline and overall consistency of results; or evidence extrapolated from studies classified as 2++.
D	Scientific evidence level 3 or 4, or extrapolated evidence from studies rated as 2 +.
Good Clinical Practice (GCP)*	Recommended practice based on clinical experience and the consensus of the editorial team.

*Sometimes the development group realises that there are some important practical aspects, which should be emphasised, and for which there is probably no scientific evidence that supports them. In general, these cases are related to some treatment aspect considered to be "good clinical practice" and usually no one would argue about them. These aspects are rated as points of good clinical practice.

Grades of Recommendation for Diagnosis-Related Questions

Recommendation	Evidence
A	Ia or Ib
B	II
C	III
D	IV

Cost Analysis

- According to a study carried out in the Spanish context, the average cost of the treatment with continuous subcutaneous insulin infusion (CSII) was € 25,523 per treated patient, considering data from 2005. A cost-utility analysis indicates that although the CSII is a more expensive technology than multiple daily injections (MDI), it is a bit more effective than MDI (assuming a gain control base of glycosylated haemoglobin (HbA_{1c}) of -0.51% in favour of the CSII therapies) with a cost/utility incremental ratio of 29,947 €/quality-adjusted life-year (QALY).
- An economic evaluation conducted in the Spanish context carried out an analysis on how to minimise costs by assuming that the 3 systems compared (syringe, prefilled pen and prefilled syringe) were equally effective in controlling the level of blood sugar. The estimated average cost for insulin injection was € 0.383 with syringe, € 0.341 with pre-filled pen, and € 0.329 with prefilled syringe, resulting prefilled pens and syringes more efficient than syringes.
- A study in people with difficulties to self-administer found that use of prefilled pens supposed savings because less insulin was wasted than with conventional syringes and assumed a lower cost associated with the time spent by nurses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The text has undergone an external review by a multidisciplinary group of professionals. The final version of the guide has been reviewed and approved by the development team.

The different scientific societies involved have been contacted:

- Federación de Asociaciones de Diabéticos de Euskadi (Federation of Diabetes Associations of the Basque Country) belonging to the

Federación de Diabéticos Españoles (Spanish Diabetes Federation)
- Sociedad Española de Diabetes (Spanish Diabetes Society)
- Sociedad Española de Endocrinología y Nutrición (Spanish Society of Endocrinology and Nutrition), who participated through the development team and the external review.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of diabetes mellitus type 1

Potential Harms

- Occurrence of hypoglycaemia (mild, moderate, or severe) and injection site reactions with pharmacological therapy
- Adverse effects of drug therapy for diabetic complications
- Islet transplantation is associated with complications related to the procedure and immunosuppression. None of these studies reported any preoperative or postoperative death as a direct result of the procedure. However, there were 38 serious adverse events in 36 patients and 18 of them required hospitalization. Complications related to the procedure were mainly intraperitoneal bleeding (9% as mean, 23% in the study of Edmonton); the portal vein thrombosis, which in most cases was partial (described in 6 of the 11 studies percentages ranging between 6 and 17%) and liver abnormalities (described in 8 of the 11 studies, ranging from 10 to 100%). As for the adverse effects of immunosuppressive therapy, 7 of 11 studies reported impairment of renal function from 17% to 50% of the patients, forcing regime change in immunosuppression between 10% and 37% of the cases. Other complications observed in an international multicenter study were mouth sores (92%), anaemia (81%), leukopenia (75%), diarrhoea (64%), headache (56%), neutropenia (53%), nausea (50 %), vomiting (42%), and acne (39%).
- Refer to the original guideline document, including Chapters 10 and 11 Appendix 10, for further details regarding specific medications.

Contraindications

Contraindications

- People with diabetes mellitus type 1 and their families should be informed that exercise is contraindicated if there are high levels of blood glucose and/or ketones in the blood or urine.
- Young people and adults with diabetes mellitus type 1 who want to practice intense physical exercise should ask their doctor in advance to rule out microvascular complications that may contraindicate it.
- It is necessary to provide information to the future pregnant woman and her partner on the need, first, to assess the situation of maternal diabetes to detect possible contraindications of gestation and, secondly, to express the convenience of active participation of both in order to achieve the preconception objectives.
- During pregnancy and in the case of having bilateral stenosis of the renal artery an angiotensin converting enzyme inhibitor drug treatment is contraindicated. In case of contraindications or intolerance to angiotensin converting enzyme inhibitors, an angiotensin II receptor antagonist treatment is recommended.

Qualifying Statements

Qualifying Statements

This clinical practice guideline (CPG) is an aid to decision making in health care. The compliance of this guide is not mandatory, nor does it replace the clinical judgment of the health care personnel.

Implementation of the Guideline

Description of Implementation Strategy

Dissemination and Implementation Strategy

Clinical practice guidelines are useful to improve the quality of care and outcomes for the patient. The big challenge now is to get the professional to adhere to the recommendations of these guidelines. This calls for an implementation strategy aimed at overcoming the existing barriers in the environment in which it will be applied.

The plan to implement the diabetes mellitus type 1 guide includes the following interventions:

1. Presentation of the guide by the health authorities to the media.
2. Presentation of the guide to the Directorate and Sub-directorate of the Primary Health Care and Specialized Care Units of the different Health Services.
3. Institutional presentation of the guide in collaboration with the Quality Agency of the Ministry of Health, Social Policy and Equality, to the different scientific and professional societies involved.
4. All presentations will highlight the educational material made for the patient in order to facilitate its distribution among all the health professionals as well as among the patients with this health problem.
5. Effective and addressed distribution to the professional groups involved (physicians specialized in Endocrinology and Nutrition, pediatric endocrinologists, diabetes nurse educators, nutritionists) to facilitate its distribution.
6. Dissemination of the guide in electronic format in the websites of the Ministry of Health, Social Policy and Equality, GuíaSalud, Osteba and the companies involved in the project.
7. Publishing of the guide in scientific magazines.
8. Setting up of criteria for good attention in contract programs and clinical management contracts, following the provisions of the guide.
9. Evaluation of the effectiveness of implantation, establishing systems to support the clinical decision, integrating the guide and the selected indicators in the computer program used in Specialized Care.

For additional information on the implications for clinical practice and proposed indicators see Chapter 13 in the original guideline document.

Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Foreign Language Translations

Mobile Device Resources

Patient Resources

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Working Group of the Clinical Practice Guideline on Diabetes Mellitus Type 1. Clinical practice guideline for diabetes mellitus type 1. Madrid (Spain): Basque Office for Health Technology Assessment, Osteba; 2012 May 1. 345 p. [644 references]

Adaptation

This guideline was partially adapted from the following sources:

- National Institute for Health and Care Excellence (NICE). Diagnosis and management of type 1 diabetes in children, young people and adults. Clinical Guideline 15 2004 Jul.
- NICE. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE technology appraisal guidance 151. Review of technology appraisal guidance 57 2008.
- Grupo de trabajo de la Guía de Práctica Clínica sobre Diabetes tipo 2. Guía de Práctica Clínica sobre Diabetes tipo 2. Madrid: Plan Nacional para el SNS del MSC Agencia de Evaluación de Tecnologías Sanitarias del País Vasco 2008;Guías de Práctica Clínica en el SNS: OSTEBA Nº 2006/08.

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Guideline Developer(s)

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GuiaSalud - National Government Agency [Non-U.S.]

Ministry of Health (Spain) - National Government Agency [Non-U.S.]

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Guideline Committee

Development Group of the Clinical Practice Guideline (CPG) on Diabetes Mellitus Type 1

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Financial Disclosures/Conflicts of Interest

All members of the Working Group, as well as those who have participated in the expert collaboration and external review, have made the declaration of interest as appears in Appendix 14 of the original guideline document.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in English and Spanish from the GuíaSalud Web site.

Availability of Companion Documents

The following are available:

- Quick reference guides summary versions of the guideline are available in several dialects from the GuíaSalud Web site.
- Methodological Manual "Elaboración de Guías de Práctica Clínica en el Sistema Nacional de Salud" (Development of Clinical Practice Guidelines in the NHS). Electronic copies: Available in Spanish from the GuíaSalud Web site.
- Updating clinical practice guidelines in the Spanish National Healthcare System: methodology handbook. Available from the GuíaSalud Web site.
- The Spanish version of the guideline is also available via a mobile application from the GuiaSalud Web site.

In addition, a variety of tools are available in the appendices of the original guideline document, including information on sweeteners, suggested menus, exchanges and equivalences, and instructions on the use of the monofilament. Proposed indicators are also available in section 13.3 of the original guideline document.

Patient Resources

The following are available:

- A patient guide for diabetes mellitus type 1 is available in Spanish from the GuíaSalud Web site.
- Information for patients: International charter of rights and responsibilities of people with diabetes. Available in Appendix 11 in the original guideline document.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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